11-26-03

1654

Attorney Docket No. 9233.54

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.
Serial No.: 09/873,899
Filed: June 4, 2001
For: *Mixtures of Insulin Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making Same*

Confirmation No.: 5139
Group Art Unit: 1654
Examiner: Russel, Jeffrey E.

November 24, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Attached is a list of documents on form PTO-1449 together with a copy of each identified document. It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. § 1.56 and Section 609 of the MPEP. This Information Disclosure Statement is submitted in accordance with 37 C.F.R. § 1.97(c), before final Office Action or Allowance.

Also attached is a Declaration of James Gordon Still under 37 C.F.R. § 1.132 (originally prepared for submission in application serial no. 10/075,097) in which Dr. Still provides information about the slides that are included on the attached PTO Form 1449 as items 76 and 81. Although applicants provide these slides to the examiner in the interest of full disclosure in accordance with applicant's duty, it is applicants' belief that these slides are not "printed publications" as set forth in 35 U.S.C. § 102(b) and are thus not prior art to the claimed invention. Applicants base this belief on a comparison of the facts in this case as set forth in Dr. Still's Declaration with the facts set forth in *Regents of the University of California v. Howmedica, Inc.* [210 U.S.P.Q. 727 (D.N.J. 1981); *aff'd,* 676 F.2d 687 (3rd Cir. 1982); copy enclosed], in which the court determined that slides shown during an oral presentation did not constitute a "printed publication" within the meaning of 35 U.S.C. § 102(b). Because the facts

reviewed by the court parallel the facts of the present application, applicants believe these slides are not prior art against the invention as claimed in the present application.

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. § 1.97(c), before final Office Action or Allowance. In accordance with the requirements of 37 C.F.R. § 1.97(c)(2), a check for the $180.00 fee specified in 37 C.F.R. § 1.17(p) is enclosed. This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

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CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR §1.10

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I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Cathy A. Schetzina

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 Of 4

Complete if Known	
Application Number	09/873,899
Filing Date	June 4, 2001
First Named Inventor	Ekwuribe
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Examiner Name	Russel, Jeffrey E.
Attorney Docket Number	9233.54

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	2002/0160938	A1	Brandenburg et al.	10/31/2002	
	2.	2003/0144468	A1	Ekwuribe et al.	07/31/2003	
	3.	2003/0087808	A1	Soltero et al.	05/08/2003	
	4.	2003/0083232	A1	Soltero et al.	05/01/2003	
	5.	2003/0069170	A1	Soltero et al.	04/10/2003	
	6.	2003/0060606	A1	Ekwuribe et al.	03/27/2003	
	7.	2003/0050228	A1	Ekwuribe et al.	03/13/2003	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages/Figures Appear	T
—	35.	EP	EP 0 511 903	B1	Wantier et al.	10/14/1998		Claims
/	36.	WO	99/65941	A1	Jones et al.	12/23/1999		

OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
—	37.	Agarwal et al. "Polymethyacrylate-based Microparticulates of Insulin for Oral Delivery: Preparation and In Vitro Dissolution Stability in the Presence of Enzyme Inhibitors" *International Journal of Pharmaceutics* 225:31-39 (2001)	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute form 1449A/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	09/873,899
				Filing Date	June 4, 2001
				First Named Inventor	Ekwuribe
				Group Art Unit	1654
(use as many sheets as necessary)				Examiner Name	Russel, Jeffrey E.
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	38.	Allaudeen et al. "Orally Active Insulin: A Single Insulin Conjugate Selected for Future Studies" 60th Annual Meeting of the American Diabetes Assoc., Atlanta, GA June 2000 (Abstract)	
	39.	Anderson et al. "HIM2, a Novel Modified Insulin, has Improved Systemic Pharmacokinetics in Normal Dogs, Compared to Unmodified Insulin" American Diabetes Association 62nd Annual Meeting June 2002 (Abstract)	
	40.	Block, Lawrence H. "Pharmaceutical Emulsions and Microemulsions" *Pharmaceutical Dosage Forms: Disperse Systems*, Vol. 2, Ed. Lieberman et al. (1996)	
	41.	Bone et al. "Successful Treatment of an Insulin Dependent Rat Model of Human Type I Diabetes with Orally Active Insulin" Program and Abstracts, 4th International Workshop on Lessons from Animal Diabetes, Omiya, Japan November 1994 (Abstract)	
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	43.	Brange and Volund "Insulin Analogs with Improved Pharmacokinetic Profiles" *Advanced Drug Delivery Reviews* 35:307-335 (1999)	
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	45.	Clement et al. "Effects of Multiple Doses of Orally Administered Hexyl Insulin M2 (HIM2) on Postprandial Blood Glucose (PPG) Concentrations in Type 1 Diabetic (T1) Patients" American Diabetes Association 62nd Annual Meeting, June 2002 (Poster)	
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	75.	Still and McAllister "Effects of Orally Active Modified Insulin in Type 1 Diabetic Patients" *Clinical Pharmacol. Therap.* 69(2): P95 (Feb. 2001) (Abstract)	
	76.	Still and McAllister "Effects of Orally Active Modified Insulin in Type I Diabetic Patients" Slide Presentation 2001 Annual Meeting of the American Society for Clinical Pharmacology & Therapeutics, Orlando, FL, March 9, 2001	
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	78.	Still et al. "Magnitude and Variability of Pharmacokinetic and Glucodynamic Responses to Modified Human Insulin Administered Orally to Healthy Volunteers" *Diabetes Research and Clinical Practice* 56:S77 (2002)	
	79.	Still et al. "Methods of Reducing Hypoglycemic Episodes in the Treatment of Diabetes Mellitus" U.S. Serial No. 10/461,199, filed 06/13/2003	
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	82.	Stocklin et al. "A Stable Isotope Dilution Assay for the In Vivo Determination of Insulin Levels in Humans by Mass Spectrometry" *Diabetes* 46(1):1-7 (Jan. 1997)	
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	85.	Vreeland et al. "Molar Mass Profiling of Synthetic Polymers by Free-Solution Capillary Electrophoresis of DNA-Polymer Conjugates" *Anal. Chem.* 73(8):1795-1803 (2001)	
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